

Remarks

I. Status of the Application and Claims

As originally filed, the present application had a total of 17 claims. In previous prosecution, all of these were cancelled and replaced with claims 18-40. In the present response, all of the previously pending claims have been cancelled and replaced with new claims 41-49.

II. The Amendments

Support for new claim 41 may be found in cancelled claims 18 and 20.

Support for new claim 45 may be found in cancelled claims 30 and 32.

Support for new claims 47 and 48 may be found in cancelled claims 39 and 40 respectively.

Support for the specific cells recited in new claim 49 may be found on page 11 of the specification, lines 5-8.

The amendments do not add new matter to the application and their entry is therefore respectfully requested.

The Rejections

I. Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph

On pages 2 and 3 of the Office Action, claims 39 and 40 are rejected under 35 U.S.C. § 112, second paragraph. The Examiner alleges that these claims are indefinite because it is not clear which transitional phrase, "comprising" or "consisting of," controls the scope of the claim. It is suggested that using the phrase "an expression vector comprising the polynucleotide of" would obviate the rejection.

In the interest of furthering the prosecution of this case, Applicants have adopted the language suggested by the Examiner and therefore respectfully submit that the present rejection has been obviated.

II. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

On pages 3-5 of the Office Action, claims are rejected under 35 U.S.C. § 112, first paragraph, based upon the allegation that they fail to meet the written description requirement of patentability. The Examiner appears to believe that the phrase “consisting essentially of” renders the claims unpatentable.

Applicants respectively traverse this rejection.

The meaning of the transitional phrase “consisting essentially of” is well-established in patent law. It is set forth in MPEP § 2111.03 as follows:

The transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristics of the claimed invention.

It is typical for this transitional phrase to be used in connection with compositions of matter (see MPEP § 2111.03, last twelve lines) and it is also very common for it to be used in patent claims directed to DNA sequences. DNA claims containing the transitional phrase have appeared in cases considered by the Federal Circuit and to Applicants’ knowledge, the court has never found the phrase to be inappropriate in and of itself.¹ In addition, the Written Description Guidelines set out by the Patent Office suggest that the transitional phrase “consisting essentially of” can sometimes be used to claim a gene where the phrase “comprising” would be inappropriate (see Example 6 in the Guidelines). Thus, Applicants submit that there is nothing inherently improper in using this transitional phrase in claiming a DNA or protein sequence.

¹ In *Amgen v. Chugai*, 18 U.S.P.Q. 2d 1016 (Fed. Cir. 1991), the court found certain claims invalid that contained this transitional phrase but the decision was based upon other considerations. In *Fiers v. Sugano*, 25 U.S.P.Q.2d 1601 (Fed. Cir. 1993), the court considered an interference count that read: “A DNA which consists essentially of a DNA which codes for a human fibroblast interferon-beta polypeptide.”

As indicated above, “consisting essentially of” limits the scope of a claim to the specific composition recited and to compositions that contain differences that do not materially affect the basic and novel characteristics of the invention. In the case of a claim to a DNA sequence encoding a protein, there are only two characteristics that can be considered basic and novel with respect to the prior art; the structure of the DNA (*i.e.*, its sequence) and its function (*i.e.*, the ability to produce a protein having a particular activity). Thus, it is Applicants’ position that trivial changes in sequence, *i.e.*, changes that do not result in a loss of novelty with respect to structure or substantially change the function of the encoded protein, are encompassed by the phrase but that more substantial changes are not. This has been reflected in the definition of the phrase provided in the application and which is referred to by the Examiner in the Office Action.

The Examiner also appears, in part, to take the position that the written description requirement can only be met if one of skill in the art can, after reading a claim, recite all of the subject matter that falls within its scope. This is an inappropriate standard that could not be met by most claims that use either the transitional phrase “consisting essentially of” or “comprising.” For example, using such a standard, a claim to a “pharmaceutical composition comprising compound X” would fail to meet the requirement because one of skill in the art could not recite all of the combinations of additional drugs and excipients that fall within the scope of the claim. A claim to a “vector comprising sequence Y” would be unpatentable because one of skill in the art could not possibly recite all of the different sequence elements that, in combination with sequence Y, could make up the claimed vector.

Applicants submit that a proper written description analysis for a claim directed to a genus is to ask whether sufficient characteristics of the genus have been defined for one of skill in the art to determine whether any given subject matter falls within its scope.² In the present application, claims are directed to the genus of all polynucleotides that are structurally substantially the same as those expressly recited in the claims and the requirement of being substantially the same is defined in terms of structure and function, *i.e.*, the genus includes any polynucleotide that is either structurally identical to one of the

² It appears from the Office Action that the Examiner may at least partially agree with this.

sequences recited or that is structurally so similar that there is no significant difference in activity. It is important to recognize that this is not merely a functional definition. A polynucleotide that is structurally substantially different from the sequences expressly recited falls outside the scope of the claims. For example, under the definition provided in the application, differences that resulted in the expression of a protein with increased or decreased activity could be considered substantial even if few in number and such polynucleotides would fall outside the scope of the claims. As a practical matter, it is well recognized in the art, that in order to maintain essential functional identity, the degree of sequence homology between any given polynucleotide and the polynucleotides expressly recited in the claims would have to be very high. It should therefore be easy for one of skill in the art to recognize whether an issue as to potential infringement might exist.

The Examiner also appears to suggest that it is not clear what particular functions must be maintained in order to meet the requirements discussed above. Applicants believe that it should be clear from the application that the function that has been attributed to the proteins encoded by the claimed polynucleotides is that of conferring multidrug resistance on cells. This can be tested in several ways including directly exposing transformed cells to drugs or using the dye exclusion assays that have been described in the Declaration submitted by Applicants with their previous response. Nevertheless, in order to remove any doubt that may exist, Applicants have amended claims so that the term “consisting essentially of” is now coupled with language requiring that proteins encoded by polynucleotides must promote multidrug resistance when expressed in a host cell. In addition, Applicants have introduced separate claims which utilize the transitional phrases: “comprising” or “consisting of.”

III. Rejection of Claims Under 35 U.S.C. § 101

On pages 5-7 of the Office Action, the Examiner rejects claims under 35 U.S.C. § 101. There are actually two separate rejections that are made. In the first, claim 40 is rejected because it allegedly fails to distinguish the claimed subject matter from that which occurs in nature. Claim 40 has now been replaced with claim 48 that refers to a host cell that “has been transformed with the expression vector of claim 47.” The act of having been

transformed, *i.e.*, transfected with a vector, should clearly distinguish the claimed host cells from cells that occur in nature.

The Examiner also rejects claims 18-26 and 30-40 based upon the allegation that they are not supported by a specific and substantial or credible utility. It appears that the Examiner did not intend to include embodiments that are directed to polynucleotides that encode a protein with the sequence of SEQ ID NO:2 within this rejection. These embodiments were the subject of the experiments described in the Declaration Under 35 U.S.C. § 1.132 previously submitted by Applicants in support of the concept (*inter alia*) that polynucleotides encoding proteins of SEQ ID NO:2 confer multidrug resistance on cells.

In the interest of furthering the prosecution of this case, Applicants have limited the amended claims so that they now only refer to proteins with the amino acid sequence of SEQ ID NO:2 (corresponding to the protein that was the subject of Dr. Frank's Declaration) and to polynucleotides which encode this protein, including those having a sequence corresponding to SEQ ID NO:10, (see page 3 of Dr. Frank's Declaration, lines 1-4). It is therefore respectfully submitted that the Examiner's rejection has been obviated.

Conclusion

In light of the amendments and arguments described above, Applicants submit that all of the Examiner's rejections have been overcome. It is therefore respectfully requested that these rejections be withdrawn and that the claims presently pending in the application be allowed.

If, in the opinion of the Examiner, a phone call may help to expedite the prosecution of this application, the Examiner is invited to call Applicants' undersigned attorney at (202) 419-7013.

Respectfully submitted,

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